DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 20, 2014

CO-INNOVATION BIOTECH CO., LTD.
HONG FENG
NO. 13, YANYUAN ROAD , TIANHE DISTRICT, GUANGZHOU, P.R.
CHINA

Re: K140748
Trade/Device Name: One Step Single/Multi-drug Test Cup
One Step Single/Multi-drug Test Dipcard
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG, DJR, DNK, JXN, LFG
Dated: July 08, 2014
Received: July 09, 2014

Dear Hong Feng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k140748

Device Name
One Step Single/Multi-drug Test Cup
One Step Single/Multi-drug Test Dipcard

Indications for Use *(Describe)*
One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard are lateral flow chromatographic immunoassays designed to qualitatively detect the presence of drugs and drug metabolites in human urine at the following cut-off concentrations:

Test	Calibrator	Cutoff Level (ng/mL)
Buprenorphine (BUP)	Buprenorphine	10
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP)	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	300
Morphine (MOP300)	Morphine	300
Propoxyphene (PPX)	Propoxyphene	300
Tricyclic Antidepressants (TCA)	Nortriptyline	1000

There are two formats: 1) Test Cup, 2) Test Dipcard. Each format may have from 1 to 5 drugs in any combination. The assays are intended for in vitro diagnostic use. They are intended for prescription use including point of care sites and over-the-counter use.

The tests may yield preliminary positive results even when prescription drugs including Buprenorphine, Propoxyphene, or Tricyclic Antidepressants are ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of these drugs. There are no uniformly recognized cutoff concentration levels for Buprenorphine, Propoxyphene, or Tricyclic Antidepressants in urine.

This assay provides only a preliminary analytical test result. Gas Chromatography/Mass spectrometry (GC/MS) or an equivalent analytical method is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Co-Innovation Biotech Co., Ltd.

Section 5 - 510(k) Summary

Date of Summary Preparation: 8/14/2014

1. Submitter's Identifications

Submitter: Co-Innovation Biotech Co.,Ltd.
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2. Correspondent's Identifications

Correspondent's Name: Co-Innovation Biotech Co.,Ltd.
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Contact Email Address: fenghongfda@126.com
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3. Name of the Device

Recommended classification regulation:

21 CFR 862.3650 Opiate test system
21 CFR 862.3620 Methadone test system
21 CFR 862.3640 Morphine Test System
21 CFR 862.3700 Propoxyphene test system
21 CFR 862.3910 Tri-cyclic Antidepressants drug test system

Device class: Class Ⅱ
Panel: Toxicology (91)
Product code: DJG,DJR,DNK,JXN,LFG
Common Name:

Buprenorphine(BUP) Test System
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine(EDDP) Test System
Morphine(MOP) Test System
Propoxyphene(PPX) Test System
Tri-cyclic Antidepressants (TCA)Test System

Proprietary names:

One Step Single/Multi-drug Test Cup
One Step Single/Multi-drug Test Dipcard

4. The Predicate Devices

K122809 Advin Multi-Drug Screen Test Dip Card
Advin Multi-Drug Screen Test Cup
Advin Multi-Drug Screen Test Cassette

5. Device Description

One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard are competitive binding , lateral flow immunochromatographic assays for qualitatively the detection of Buprenorphine, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine, Morphine, Propoxyphene, Tri-cyclic Antidepressants and their metabolites at or above the cut-off levels as indicated. The tests can be performed without the use of an instrument.
Test Cup and Test Dipcard use identical test strips made with same chemical formulation and manufacturing procedures.

6. Intended Use of Device

One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard are lateral flow chromatographic immunoassays designed to qualitatively detect the presence of drugs and drug metabolites in human urine at the following cut-off concentrations:

Test	Calibrator	Cut-off level
Buprenorphine(BUP)	Buprenorphine	10ng/mL
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine(EDDP)	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	300 ng/mL
Morphine(MOP300)	Morphine	300 ng/mL
Propoxyphene(PPX)	Propoxyphene	300 ng/mL
Tri-cyclic Antidepressants (TCA)	Nortriptyline	1000 ng/mL

There are two formats: 1) Test Cup, 2) Test Dipcard. Each format may have from 1 to 5 drugs in any combination. The assays are intended for in vitro diagnostic use. They are intended for prescription use including point of care sites and over-the-counter use.
The tests may yield preliminary positive results even when prescription drugs including Buprenorphine, Propoxyphene, or Tricyclic Antidepressants are ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of these drugs. There are no uniformly recognized cutoff concentration levels for Buprenorphine, Propoxyphene, or Tricyclic Antidepressants in urine.
This assay provides only a preliminary analytical test result. Gas Chromatography/Mass spectrometry (GC/MS) or an equivalent analytical method is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

7. Comparison to Predicate Devices:

A summary comparison of features of the One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard and the predicate devices is provided in the following Table：

Item	Device	Predicate （K122809）
Indication for use	Qualitative detection of drugs-of-abuse in urine （Buprenorphine, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine, Morphine , Propoxyphene, Tri-cyclic Antidepressants)	Same （but the number of drugs detected different)
Intended Users	Over the Counter (OTC) Use and Prescription Use	Over the Counter (OTC) Use and Prescription Use
Specimen	Urine	Same
Cutoff	Buprenorphine:10 ng/mL EDDP:300 ng/mL Morphine:300 ng/mL Propoxyphene:300 ng/mL Tri-cyclic Antidepressants:1000 ng/mL	Same
Read time	5 minutes	Same
Results	Qualitative	Same
Methodology	Competitive binding, Lateral flow immunochromatographic assay based on the principle of antigen antibody immunochemistry	Same
Configuration	Dipcard and Cup	Cassette,Dip Card and Cup

Remark:

1、 The subject devices have all features of the predicate device except the number of drugs detected . This difference do not affect the performance characteristics of the subject devices.

8. Performance Data:

Accuracy

Single drug Test:

80 clinical urine specimens for each drug were analyzed by GC/MS, LC/MS, or HPLC and by one lot of the corresponding One Step Single drug Test Cup. Samples were divided by concentration into five categories: drug free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
BUP	+	0	0	1	5	35	80

	–	35	0	4	0	0	
EDDP	+	0	0	1	7	33	80
	–	33	1	5	0	0	
MOP	+	0	0	1	5	35	80
	–	31	2	6	0	0	
PPX	+	0	0	1	6	34	80
	–	33	1	5	0	0	
TCA	+	0	0	0	5	34	80
	–	35	0	5	1	0	

Analysis of Discordant Results with One Step Single drug Test Cup

One Step Single drug Test Cup			GC/MS Analysis	
Drug Test	Cutoff (ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
BUP**	10	Positive	7.8	Buprenorphine
EDDP	300	Positive	285	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine
MOP	300	Positive	275	Morphine
PPX	300	Positive	269	Propoxyphene
TCA*	1000	Negative	1138	Nortriptyline

(TCA*:TCA was based on HPLC data.BUP**:BUP was based on LC/MS data.)

80 clinical urine specimens for each drug were analyzed by GC/MS, LC/MS, or HPLC and by one lot of the corresponding One Step Single drug Test Dipcard. Samples were divided by concentration into five categories: drug free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
BUP	+	0	0	1	5	35	80
	–	35	0	4	0	0	
EDDP	+	0	0	1	7	33	80
	–	33	1	5	0	0	
MOP	+	0	0	1	5	35	80
	–	31	2	6	0	0	
PPX	+	0	0	1	6	34	80
	–	33	1	5	0	0	
TCA	+	0	0	0	5	34	80
	–	35	0	5	1	0	

Analysis of Discordant Results with One Step Single drug Test Dipcard

One Step Single drug Test Dipcard			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
BUP**	10	Positive	7.8	Buprenorphine
EDDP	300	Positive	285	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine
MOP	300	Positive	275	Morphine
PPX	300	Positive	269	Propoxyphene
TCA*	1000	Negative	1138	Nortriptyline

(TCA*:TCA was based on HPLC data.BUP**:BUP was based on LC/MS data.)

Multi-drug Test:

80 clinical urine specimens for each drug were analyzed by GC/MS, LC/MS, or HPLC and by one lot of the corresponding One Step Multi-drug Test Cup. Samples were divided by concentration into five categories: drug free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
BUP	+	0	0	1	5	35	80
	–	35	0	4	0	0	
EDDP	+	0	0	1	7	33	80
	–	33	1	5	0	0	
MOP	+	0	0	1	5	35	80
	–	31	2	6	0	0	
PPX	+	0	0	1	6	34	80
	–	33	1	5	0	0	
TCA	+	0	0	0	5	34	80
	–	35	0	5	1	0	

Analysis of Discordant Results with One Step Multi-drug Test Cup

One Step Multi-drug Test Cup			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
BUP**	10	Positive	7.8	Buprenorphine
EDDP	300	Positive	285	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine
MOP	300	Positive	275	Morphine
PPX	300	Positive	269	Propoxyphene
TCA*	1000	Negative	1138	Nortriptyline

(TCA*:TCA was based on HPLC data.BUP**:BUP was based on LC/MS data.)

80 clinical urine specimens for each drug were analyzed by GC/MS, LC/MS, or HPLC and by one lot of the corresponding One Step Multi-drug Test Dipcard. Samples were divided by concentration into five categories: drug free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
BUP	+	0	0	1	5	35	80
	–	35	0	4	0	0	
EDDP	+	0	0	1	7	33	80
	–	33	1	5	0	0	
MOP	+	0	0	1	5	35	80
	–	31	2	6	0	0	
PPX	+	0	0	1	6	34	80
	–	33	1	5	0	0	
TCA	+	0	0	0	5	34	80
	–	35	0	5	1	0	

Analysis of Discordant Results with One Step Multi-drug Test Dipcard

One Step Multi-drug Test Dipcard			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
BUP**	10	Positive	7.8	Buprenorphine
EDDP	300	Positive	285	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine
MOP	300	Positive	275	Morphine
PPX	300	Positive	269	Propoxyphene
TCA*	1000	Negative	1138	Nortriptyline

(TCA*:TCA was based on HPLC data.BUP**:BUP was based on LC/MS data.)

Other Information About Performance Characteristics:

The performance characteristics of One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard were evaluated by precision study, sensitivity study, specificity and cross reactivity study, interference study, stability study and home use consumer study. The study results indicate that One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard perform satisfactorily when used according to the package inserts.

10. Conclusion:

One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard are substantially equivalent to Advin Multi-Drug Screen Test Dip Card, Advin Multi-Drug Screen Test Cup and Advin Multi-Drug Screen Test Cassette.

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